

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE
PAULSBORO DERAILMENT CASES**

**MASTER DOCKET NO.:
13-CV-784 (RBK/KMW)**

ALICE BREEMAN *et al.*,

Plaintiff,

vs.

**CONSOLIDATED RAIL
CORPORATION, *et al.*,**

Defendants.

**DEFENDANTS CONSOLIDATED RAIL CORPORATION, NORFOLK SOUTHERN
RAILWAY COMPANY AND CSX TRANSPORTATION, INC.'S
REPLY MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE
EXPERT REPORT AND TESTIMONY OF OMOWUNMI OSINUBI, M.D.**

Filed on behalf of Defendants,
Consolidated Rail Corporation,
Norfolk Southern Railway Company
and CSX Transportation, Inc.

Counsel of Record for These Parties:

Brian D. Pagano, Esquire

BURNS WHITE LLC
1800 Chapel Avenue West, Suite 250
Cherry Hill, NJ 08002
(856) 382-6006

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I. PRELIMINARY STATEMENT

Plaintiff has failed to satisfy her burden of demonstrating that Dr. Osinubi's opinions and methodology satisfy the requirements of *Daubert* and Fed. R. Evid. 702. As an initial matter, Plaintiff's Opposition includes a declaration of Dr. Osinubi that blatantly attempts to fill the holes in her opinions - an implicit admission that her methodology for determining causation in this matter is lacking. However, Dr. Osinubi's declaration has been submitted in contravention of the rules and should be disregarded.. Likewise, while ignoring applicable case law and failing to distinguish the cases relied upon by Defendants, Plaintiff instead cobbles together a protracted version of the "facts," coupled with hundreds of pages of irrelevant and improper exhibits. However, nothing in these voluminous "facts" or exhibits materially relates to the issue of whether Dr. Osinubi's opinions are admissible under Rule 702 and *Daubert* – the subject of Defendants' motion.

Further, Plaintiff's suggestion that any deficiencies in Dr. Osinubi's opinions are better left to cross examination ignores controlling law. As this Court is aware, it must serve as a gatekeeper to insure that expert evidence is reliable. An analysis of Dr. Osinubi's proffered opinions and underlying methodologies, which *Daubert* mandates, reveals that her speculative opinion that Plaintiff's brief, acute exposure to vinyl chloride caused or exacerbated the medical problems allegedly suffered by Plaintiff, as well as the need for medical monitoring, is unreliable and unsupported.

II. LAW AND ARGUMENT

A. Dr. Osinubi Relies On The NTSB Report, Contrary To 49 U.S.C. § 1154(b).

Plaintiff's Opposition is an exercise in avoidance. It blatantly ignores the cases cited in Defendants' motion holding that an expert cannot rely upon information contained in an NTSB report. *See Louisiana ex rel. Dept. of Transp. & Dev. v. Kition Shipping Co., Ltd.*, 653 F.Supp.2d

633, 647-48 (M.D. La. 2009); *Credle v. Smith and Smith, Inc.*, 42 F. Supp. 3d 596 (D.N.J. 2013). Nothing can be clearer than the Congressional mandate of 49 U.S.C. § 1154(b), which prohibits the use of an NTSB report. Plaintiff's veiled attempt to introduce parts of the report through her expert is merely a "back door" attempt to circumvent the statute. *Dowe v. National Railroad Passenger Corp.*, 2004 WL 887410 at *6 (N.D. Ill. April 26, 2004).

Plaintiff's assertion that Dr. Osinubi's reliance on the NTSB report was merely a "casual reference," or otherwise permissible because she also relied on "a mountain of other exposure-levels evidence," is wholly without merit. Pl. Opp. at 17, 18. Not only does Plaintiff fail to cite to any case law in this regard, but her testimony in this matter makes clear that her opinions on the alleged exposure levels in this case were based in large part on the NTSB findings. *See* Osinubi Dep. 1 at 91, attached to Def. Mem. at Exhibit A. ("The NTSB said it, the levels were very high."). The prejudicial nature of such statements and opinions cannot be overstated.

B. Deficiencies In The Osinubi Report Must Be Considered At This Stage Of The Proceedings And Not At Trial.

It is undisputed that Rule 702 grants this Court broad discretion to determine the admissibility of expert evidence. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 148 (1999). The Court must act as a "gatekeeper" to ensure that proposed expert testimony is not only relevant, but also reliable. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993). Plaintiff bears the burden of demonstrating that the proffered expert satisfies the requirements for admission. *In re TMI Litig.*, 193 F.3d 613, 663 (3d Cir. 1999). Undoubtedly, she has failed. Rather than engage in the work required to satisfy the Rule 702 and *Daubert*, Plaintiff suggests that questions about any defects in Dr. Osinubi's methodology "go to weight rather than admissibility." Pl. Opp. at 1. Plaintiff's unsupported claim is wrong. The threshold question of admissibility must be ruled on by the Court, not simply handled through cross-

examination. Indeed, the very point of Rule 702 and the requirements of *Daubert* are to prevent unreliable “expert” evidence from reaching the jury in the first place. *Kannankeril v. Terminix Int’l*, 128 F.3d 802, 809 (3d. Cir. 1997) (“[I]ssues of credibility arise *after* the determination of admissibility.”) (emphasis added). Accordingly, Plaintiff’s argument that any deficiencies in Dr. Osinubi’s methodology should be determined by the jury has no merit.

C. Dr. Osinubi’s Declaration Should Be Stricken, As It Improperly Seeks To Correct Errors Of Omission In Her Initial Reports.

In what is tantamount to an admission that her original opinions were insufficient to pass muster under *Daubert* and its progeny, Plaintiff’s Opposition is supported by a thirty (30) page declaration of Dr. Osinubi. When fairly read, the declaration is really a supplemental expert report, submitted without leave of court, which seeks to improperly inject new grounds and medical literature supporting her opinion - significantly only after her deposition and Defendants’ motion revealed substantial flaws with her methodology. Such a tactic unfairly prejudices Defendants and violates both the letter and spirit of this Court’s scheduling orders, as well as Fed. R. Civ. P. 26(e).

Dr. Osinubi’s declaration constitutes nothing more than an impermissible attempt to strengthen her existing opinion and bolster her inadequate and incomplete report. While Fed. R. Civ. P. 26(e) recognizes that parties have an obligation to supplement expert reports in a timely manner, if the party learns that in some material respect the report is incomplete or incorrect, such supplemental disclosures are “only for the narrow purpose of correcting inaccuracies or adding information that was not available at the time of the initial report. ...” *Sancom, Inc. v. Quest Comm. Corp.*, 683 F.Supp.2d 1043, 1062-63 (D.S.D. 2010). A supplemental report may be rejected where it is offered to rebut an argument raised in a motion, or was served merely because a party simply wished to supplement. *See, e.g., In re TMI Litig.*, 193 F.3d 613 (3d Cir.

1999)(upholding the exclusion of supplemental expert reports - including some that were submitted in response to motions *in limine* - as untimely); *Collier v. Bradley Univ.*, 113 F. Supp. 2d 1235, 1242 (C.D. Ill. 2000) (striking supplemental expert report submitted in opposition to defendant's *in limine* motion because additional information should have been included in original report). To permit such unfettered supplementation "would create a system where preliminary reports could be followed by supplementary reports and there would be no finality to expert reports, as each side, in order to buttress its case or position, could 'supplement' existing reports and modify opinions previously given." *Beller v. United States*, 221 F.R.D. 696, 701 (D.N.M.). All of this would also interfere with the Court's ability to set case management deadlines, "because new reports and opinions would warrant a new round of consultation with one's own expert and virtually require new rounds of depositions." *Id.* at 701-02.

Here, Dr. Osinubi's declaration is not an attempt to remedy inadvertent factual errors or amend her report based on information not previously available to her. Rather, she is specifically trying to fill the numerous gaps in her reports that were exposed during her deposition and Defendants' motion to exclude her. As a result, her declaration should be stricken from the record pursuant to Rule 26(e) and this Court's Scheduling Orders.

D. Dr. Osinubi's Methodology is Not Generally Accepted.

In an attempt to demonstrate that Dr. Osinubi's methodology and opinions are reliable under *Daubert* and its progeny, Plaintiff simply states that "Dr. Osinubi used a well-established and generally accepted methodology" - as if the fact that Plaintiff alleges it makes it so. Pl. Opp at 18. Not surprisingly, Plaintiff again provides no citation to any peer-reviewed scientific literature where Dr. Osinubi's "method" has been discussed and validated, instead insisting that

because the New Jersey Department of Health (“NJ DOH”) allegedly used the same circular reasoning as Dr. Osinubi, that it somehow validates her methodology. Pl. Opp. at 18-19.

However, as established in Defendants’ opening memorandum, the NJ DOH report is not a peer-reviewed publication, but rather a poor quality survey administered to Paulsboro residents after the derailment. *See* Weed Declaration; Exhibit A at 11-15. The fact that Dr. Osinubi failed to recognize the methodological flaws of the NJ DOH survey also explains why she considers her own subjective approach to be a “well-established and generally accepted methodology.” However, as explained in Defendants’ opening memorandum and herein, it is not.

Also without merit is Plaintiff’s unsupported contention that “the Bradford Hill factors do not apply in cases focusing on acute exposure.” Pl. Opp. at 24. Although Plaintiff cites to a number of cases for the proposition that a strong temporal relationship and immediate symptomology can support a conclusion of causation, those cases are distinguishable from the instant case. *See, e.g., Cavallo v. Star Enter.*, 892 F.Supp. 756 (E.D. Va 1995). As Sir Bradford Hill stated, “if specificity exists we may be able to draw conclusions without hesitation.” *See* The Environment and Disease: Association or Causation. However, here, there is no specificity of association, or single cause, of the injuries alleged, particularly when most of the injuries to Plaintiff were existing prior to the derailment. Accordingly, application of the Bradford Hill criteria is necessary and appropriate to determining if there is another way of explaining the set of facts present in this case.

Finally, it is worth noting that in their opening memorandum, Defendants clearly established that Dr. Osinubi’s opinions were premised upon inadequate data and faulty assumptions contrary to the circumstances surrounding the derailment. Plaintiff wholly failed to address this argument, instead dismissing them out of hand with statements such as “there is no

need to discuss Defendants’ pointless attack on the ALOHA model.” Pl. Opp. at 20. In fact, given Dr. Osinubi’s extensive reliance on the ALOHA model, Defendants’ attack was far from pointless. The ALOHA model was not an actual reflection of the alleged exposures, but instead, a “worst case” modeling that did not incorporate the actual conditions at the time of the derailment. Indeed, the recurring theme of Plaintiff’s Opposition is to blankly discredit Defendants’ points, perhaps in the hope that this Court will do the same. However, as part of its role as gatekeeper, the district court must ensure that the underlying facts and/or data upon which a proffered expert’s opinion are based are reliable in and of themselves. If an expert’s opinion is based on unreliable facts, the opinion must be excluded. *See In re TMI Litig.*, 193 F.3d at 697.

E. Temporal Relationship, Without More, Fails To Establish Causation.

Defendants do not dispute that a limited amount of vinyl chloride was released following the derailment. However, merely documenting the existence of vinyl chloride does not prove actual exposure to Plaintiff, nor does it prove that Plaintiff received a sufficient dose to cause or exacerbate her alleged injuries, or increase her risk of cancer. Causation requires a showing of exposure and dose levels sufficient to cause the injuries claimed. *Allen v. Pennsylvania Eng’g Corp.*, 102 F.3d 194, 199 (5th Cir. 1996); *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1107 (8th Cir. 1996); *Amorgianos v. National Railroad Passenger Corp.*, 137 F. Supp. 2d 147, 163 (E.D.N.Y. 2001) (finding that in a toxic tort case, expert testimony on general causation must include testimony on exposure, dose, duration and causation to satisfy *Daubert*).

Nevertheless, Plaintiff contends that “[c]ausation can be established in the absence of a precise measurement.” Pl. Opp. at 22. Among other cases, Plaintiff clings to *Kannankeril v. Terminix Int’l. Inc.*, 128 F.3d 802, 809 (3rd Cir. 1997), and advocates an overly broad and unfounded interpretation of that case. *Kannankeril* does not stand for the blanket proposition that

there is no need to show the precise level of exposure to prove causation. The *Kannankeril* Court explicitly noted that the physician there had “sufficient knowledge of exposure” because he reviewed and considered application records for the pesticide which showed when, how much, and where the pesticide had been applied. *Id.* at 808. The plaintiff’s exposure from the repeated pesticide applications inside the *Kannankeril* home was far more readily inferred than Plaintiff’s unknown exposures here in an outdoor setting where there were numerous variables at play (i.e. wind, terrain, atmospheric conditions, Plaintiff’s alleged location, etc.). Moreover, general causation was not disputed in *Kannankeril*, and plaintiff developed toxic effects of the pesticide that were “well recognized by the scientific community.” *Id.* at 809. Additionally, in *Kannankeril*, the court relied on the fact that the defendant never raised any other theories of causation to challenge the expert’s opinion. *Id.* at 808. Here other viable theories of causation have been raised by Defendants (specifically, smoking, obesity, diabetes, other possible environmental exposures, etc.). Accordingly, Plaintiff’s reliance on *Kannankeril* is misplaced.

Likewise, Plaintiff’s reliance upon the perceived temporal relationship between Plaintiff’s alleged exposure and onset of injury or symptoms cannot fill the gaping analytical void in Dr. Osinubi’s analysis. Admittedly, as a part of the causation picture, an expert may draw conclusions about the effects of exposure to a chemical based upon the temporal connection between exposure and the onset of symptoms. *Heller v. Shaw Indus.*, 167 F.3d at 146, 158 (3d Cir. 1999). However, temporal relationship may not supplant scientifically reliable data supporting the relationship -- the ultimate conclusion, must always fit the data that allegedly supports it. *Id.* In this case, not only does Dr. Osinubi have no data supporting her opinions that Plaintiff’s brief and acute exposure to vinyl chloride or its decay products could or did cause Plaintiff’s injuries, but the wealth of scientific data manifestly refutes that such limited and acute

exposures could cause the alleged injuries. Accordingly, Plaintiff's claims that she was injured, or that her existing maladies were exacerbated after the derailment, do not suffice as a scientifically reliable basis for concluding that the alleged exposures were the cause. Instead of reasoning from known facts to reach a conclusion, Dr. Osinubi has reasoned from an end result in order to hypothesize what was unknown. She assumes that Plaintiff's injuries were caused by her alleged vinyl chloride exposure, and back-fills this assumption with the hypothesis that the temporal proximity between the development of the injuries and the alleged exposure proves a connection between these events. Her opinions are is nothing more than unsupported speculation that must be excluded from evidence under Rule 702 and *Daubert*.

F. A Causation Opinion Cannot Be Untethered To Any Scientific Evidence.

To explain the lack of published literature linking the alleged exposures to Plaintiff's alleged injuries, Plaintiff cites *Heller*, 167 F.3d at 155, for the proposition that in certain instances, a medical expert need not cite published studies on general causation to make a reliable causation determination. However, the *Heller* court stated that some basis must be given to support the causation testimony. *Id.* at 157-159. The plaintiff's expert, who had identified no literature and had not eliminated other potential causes, was relying solely on a temporal connection. *Id.* Ultimately, the court held that the expert was properly excluded, reasoning that his methodology was "based on speculation and estimation," and none of his assumptions appeared to be "supported by reliable scientific methods or the reliable application of any valid theory." *Id.* at 162-63. Accordingly, Plaintiff cannot save Dr. Osinubi's causation opinion as to acute vinyl chloride exposure and long-term respiratory disease (as opposed to brief respiratory discomfort) by relying on studies discussing "short term respiratory effects," and analogizing to studies of other "respiratory irritants." Pl. Opp. at 30-31. Likewise, in the absence of literature

supporting her opinions and a proper differential diagnosis, Dr. Osinubi's general causation and medical monitoring opinions next discussed are similarly speculative and unreliable.

G. Dr. Osinubi's Risk-Of-Cancer and Medical-Monitoring Opinions Lack Support And Are Therefore Inadmissible.

After Dr. Osinubi admitted that there is no scientific evidence linking acute vinyl chloride exposure to a significant increased risk of cancer in humans, *see* Osinubi Dec. 11, 2014 Rpt. at 22; Osinubi Truluck Dep. at 159 (attached as Exhibit 1), Plaintiff now seeks to exploit prophylactic regulatory and advisory standards to support Dr. Osinubi's general causation and medical monitoring opinions. Pl. Opp. at 34-36. Courts around the country have refused to rely on such standards, however, because "[r]egulatory and advisory bodies such as IARC, OSHA and EPA" use a "threshold of proof [that] is reasonably lower than that appropriate in tort law" when making "prophylactic rules." *Allen*, 102 F.3d at 198 (quoting *Wright*, 91 F.3d at 1107).

The National Academy of Sciences ("Academy") calculations and EPA risk assessments on which Plaintiff relies "intentionally encompass the upper range of possible risks," and "do not provide information about actual risk or causation." *Gates v. Rohm & Haas Co.*, 265 F.R.D. 208, 226-27 (E.D. Pa. 2010) (citation omitted).¹ Moreover, the Academy expressly cautions that "there is great uncertainty in those estimates, and they conflict with epidemiologic data on occupational exposure to VC." Committee on Acute Exposure Guideline Levels, *Acute Exposure Guideline Levels for Selected Airborne Chemicals: Volume 11* at 259 (2012), available at http://www.epa.gov/opptintr/aegl/pubs/vinyl_chloride_volume_11.pdf. In sum, these regulatory

¹ The same is true of the OSHA action levels Plaintiff cites, Pl. Opp. at 34, and the Acute Exposure Guideline Levels (AEGLs) upon which Dr. Osinubi relies. *Johnson v. Arkema, Inc.*, 685 F.3d 452, 463-64 (5th Cir. 2012) (recognizing that AEGLs, like other regulatory standards, "are not necessarily reliable in all toxic tort cases," and holding that, in failing to provide the underlying basis for the experts' reliance on them, the experts' opinions are inadmissible); *See Nat'l Bank of Commerce v. Associated Milk Producers, Inc.*, 22 F. Supp. 2d 942, 961 (E.D. Ark. 1998), *aff'd*, 191 F.3d 858 (8th Cir. 1995) (holding that "regulatory agencies employ a different perspective in setting 'action levels' than do courts imposing tort liability").

standards and exposure levels “are inappropriate for use in determining whether medical monitoring should be instituted” because they “overstate the *actual* risk.” See *O’Neal v. Dep’t of the Army*, 852 F. Supp. 327, 333 (M.D. Pa. 1994).²

Dr. Osinubi also relies on a 1998 study of 29 individuals exposed to vinyl chloride after a 1996 train derailment, explosion, and fire in Germany. Pl. Op. at 35-36 (citing E. Huttner, T. Nikolova, *Cytogenetic analysis of peripheral lymphocytes in a population exposed to vinyl chloride through an accidental release into the environment*, *Toxicol. Lett.* 96/97 (1998) 143-48.

Dr. Osinubi’s reliance on this study is unfounded. First, there is no evidence that the type of genetic changes discussed in that study is associated with a significant increased risk of liver cancer.³ Indeed, the other studies cited by Dr. Osinubi in her most recent declaration confirm this.⁴ The Anderson study does not address whether chromosomal aberrations increase cancer

² Plaintiff takes out of context the fact that Dr. Greenberg, the Railroad Defendants’ medical expert and toxicologist, used the EPA algorithm to calculate a “theoretical increased risk of cancer” based on vinyl chloride levels observed after the Paulsboro derailment. See Pl. Opp. at 35 n.15; see also Greenberg General Causation Report at 22 (attached as Exhibit 2). As Dr. Greenberg makes quite clear in his report: “For the purposes of risk assessment, it is possible to calculate ***the theoretical increased risk of cancer*** from an acute duration exposure ***despite the evidence in occupational studies that short-term exposure to vinyl chloride does not increase the prevalence of tumors.***” Greenberg Rpt. at 22 (emphasis added). Dr. Greenberg’s calculations demonstrate that not even these theoretical and highly-protective regulatory risk estimates suggest that the acute exposure levels observed in Paulsboro would increase the risk of liver cancer. *Id.*

³ Dr. Osinubi originally opined that vinyl chloride exposure has also been associated with lung cancer but later withdrew this opinion. Osinubi Dep. at 116-17, 234-36 (acknowledging that the current IARC monograph does not recognize any lung cancer association). Accordingly, she is now only recommending medical monitoring for liver cancer based on Plaintiff’s exposure to vinyl chloride.

⁴ See D. Anderson *et al.*, *Issues relevant to the assessment of chemically induced chromosome damage in vivo and their relationship to chemical mutagenesis*, *Mutation Research* 90 (1981) 261-272 (attached as Exhibit 3); S. Bonassi, *et al.*, *Are Chromosome Aberrations in Circulating Lymphocytes Predictive of Future Cancer Onset in Humans?* *Cancer Genet Cytogenet* 79: 133-35 (1995) (attached as Exhibit 4); H. Norppa *et al.*, *Chromosomal aberrations and SCEs as biomarkers of cancer risk*, *Mutation Research* 600 (2006) 37-45 (attached as Exhibit 5).

risks. The Bonassi and Norppa studies conclude that a high level of chromosomal aberrations is “generally predictive of increased cancer risk” but do not link such genetic changes to an increased risk of liver cancer. Indeed, none of the studies cited by Dr. Osinubi discuss liver cancer at all.⁵

Second, and even more tellingly, Dr. Osinubi does not even acknowledge a later study by many of the same authors involving the same exposed and control populations that found no significant difference in the frequency of mutations in the HPRT gene. *See* R. Becker, T. Nikolova, I. Wolff, D. Lovell, E. Huttner, H. Foth, *Frequency of HPRT mutants in humans exposed to vinyl chloride via an environmental accident*, *Mutation Research* 494 (2001) 87-96 (attached as Exhibit 6). Although it has now been almost twenty years since the 1996 derailment, there is no epidemiological data suggesting a higher incidence of cancer (or known mutations that lead to liver cancer) in that exposed group.

Last, Plaintiff does nothing to support the medical necessity of the proposed medical monitoring. Absent any peer-reviewed studies showing that the specific medical monitoring Dr. Osinubi recommends is medically beneficial because of acute exposure to vinyl chloride, her opinion does not withstand the *Daubert* test. *In re Ingram Barge Co.*, 187 F.R.D. 262, 266 (M.D. La. 1999).

⁵ For this reason, it is not surprising that Plaintiff provides the court with only the abstracts to these studies and not the studies themselves. *See* Osinubi Dec. ¶ 50 (referring the court to abstracts attached as Exhibit CC to Plaintiff’s *Daubert* opposition). The cancers specifically discussed in these papers include respiratory tract cancers, digestive tract cancers, and lymphatic and hematopoietic tissue cancers. *See* Bonassi at 134; Norppa at 40; *see also* P. Rossner et al, *Chromosomal Aberrations in Lymphocytes of Healthy Subjects and Risk of Cancer*, *Environmental Health Perspectives* 113 (2005) 517, 519 (providing data used in Norppa study) (liver cancer not included in table listing cancer sites associated with chromosomal aberrations). Critically, these papers do not address the causes of chromosomal aberrations or suggest that vinyl chloride is associated with any of the cancers observed. As explained in the Railroad Defendants’ opening brief, the only cancer that has ever been associated with vinyl chloride is liver cancer (and then only after many years of exposure). *See* Br. at 22-24.

III. CONCLUSION

For the foregoing reasons, Defendants, Consolidated Rail Corporation, Norfolk Southern Railway Company and CSX Transportation, Inc., respectfully request that this Honorable Court exclude the proffered expert testimony of Omowunmi Osinubi, M.D.

Respectfully Submitted,

/s/ Brian D. Pagano

Brian D. Pagano, Esquire

BURNS WHITE LLC

1800 Chapel Avenue West, Suite 250

Cherry Hill, NJ 08002

(856) 382-6012

Email: bdpagano@burnswwhite.com

Attorney for Defendants,

Consolidated Rail Corporation, Norfolk Southern

Railway Company and CSX Transportation, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of July, 2015, a copy of the within Reply Memorandum of Law in Support of their Motion to Exclude the Expert Report and Testimony of Omowunmi Osinubi, M.D. was served on all counsel of record via efile.

BURNS WHITE LLC

By: /s Brian D. Pagano
Brian D. Pagano, Esquire
1800 Chapel Avenue West, Suite 250
Cherry Hill, NJ 08002
(856) 382-6012

*Attorneys for Defendants,
Consolidated Rail Corporation, Norfolk
Southern Railway Company, and CSX
Transportation, Inc.*